BIOGNOST®

WARTHIN STARRY KIT

CE IVD *In vitro* diagnostic medical device Classified acc. to Regulation (EU) 2017/746 - **Class A** device

Five-reagent kit for staining *Helicobacter pylori*

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30708STARVF	
EMDN code	W01030708	
REF **Catalogue number**	**Volume**	**UDI-DI number**
WS-12T	up to 48 tests	03858890000733

Intended use and test principle

BioGnost's Warthin Starry kit enables staining histology sections and *Helicobacter pyilori* visualization in a simple way and in a few steps. The kit is distinctive because it contains 12 containers with gelatin. They can also be used for practical incubation and section staining. By adding other reagents it is possible to create active developing solution used for immersing sections and simultaneous staining of 1 to 4 sections. Staining using Warthin Starry kit is based on reducing silver nitrate to silver using hydroquinone. The formed silver is deposited on the surface of *Helicobacter pylori*. The microscopic image shows the bacteria stained dark brown to black, the cells are stained yellow-brown, and the nuclei brown. The bacteria may be detected in mucus of surface epithelium, in apical glands of the stomach, and in mucosa of the stomach.

Product description

- **WARTHIN STARRY KIT** – Five-reagent kit for staining *Helicobacter pylori* in histologic paraffin sections

The kit contains:	12 tests for 12-48 sections (WS-12T)	Storage temperature
Acid solution	500 mL (KOT-OT-500)	15-25°C
Silver nitrate, crystals	5 g (SNP-P-5)	15-25°C
Silver nitrate, WS solution	3 mL (SNWS-OT-3)	2-8°C
Gelatin, solution (in transport / incubation container)	12 x 8 mL (GEL-OT-8)	2-8°C
Hydroquinone, solution	5 mL (HQ-OT-5)	2-8°C

CAUTION:

Adhere to the following rules in order to achieve the best results:
- use distilled or demineralized high purity water **WITHOUT** any chlorine
- use completely clean laboratory glassware
- do not touch the sections / be in contact with metal objects (scissors, tweezers etc.) during staining

Additional reagents and materials that can be used in staining

- Fixative agents such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydration/rehydration agents such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95, and Histanol 100
- Clearing agents, such as BioClear xylene or BioClear New, an aliphatic hydrocarbon-based xylene substitute
- Infiltration and embedding agents such as BioGnost's granulated paraffins BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue
- Microscopic slide covering agents and cover glass mountants such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount New Low, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount DPX New, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- Immersion media such as BioGnost's Immersion Oil, Immersion Oils types A, C, FF, 37, or Immersion Oil Tropical Grade

Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 μm thin slices and mount on a VitroGnost microscope slide

NOTE

Apply the reagent to completely cover the section.

Sample staining procedure

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Preparation of **impregnation solution:** add Silver nitrate, crystals into the bottle with Acid solution, and dissolve them by rotating the bottle.	
	Note: prepared impregnation solution is stable for at least 1 year if stored at temperature of 2-8°C. Let the solution reach room temperature before each use (only the volume to be used for staining). In time small black spots may appear at the bottom of the solution; they do not influence staining. We do not recommend filtrating the solution because impurities from filter paper may contaminate the solution.	
6.	Pour 40 ml of impregnating solution into the staining jar (we recommend Coplin staining jars) Note: do not reuse the impregnating solution	
7.	Impregnate 1 to 4 sections by immersing them into the impregnating solution. Incubate in a dark room at + 50 °C	40 min
8.	Cool the sections down to room temperature	
9.	**Very important:** Prepare the **developing solution** during the last 12 minutes of incubation in the impregnating solution. Heat the container with gelatin in transport / incubation container at +50 °C for 10 min. Add 4 drops of Silver nitrate, WS solution into the container with dissolved gelatin. Mix shortly by rotating the container. Add 7 drops of Hydroquinone, solution and stir again.	

10.	Stain the sections by immersing them into the container with developing solution and incubate at +50 °C in an upright position. Macroscopically check the sections and stop the incubation after the sections are stained yellow-brown	5-10 minutes
11.	Rinse well in warm running water	2 min
12.	Dehydrate in 70% alcohol (Histanol 70)	2 exchanges, 30 seconds each
13.	Dehydrate in 95% alcohol (Histanol 95)	2 exchanges, 30 seconds each
14.	Dehydrate in 100% alcohol (Histanol 100)	30 seconds
15.	Dehydrate in 100% alcohol (Histanol 100)	2 min
16.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing, apply an appropriate BioMount covering/mounting medium. If BioClear xylene was used, use one of BioGnost's xylene-based mountants (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate mountant is BioMount New. Cover the section with a VitroGnost cover glass.

Result

Black – *Helicobacter pylori*
Brown-red – background

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instruction for use may cause differences in staining results.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, staining, mounting of the slides, and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards. To avoid a false result, it is recommended to use a positive and negative control.

If a serious incident occurs during use of this product or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label and in the Safety Data Sheet, which is available on request.

Storage, stability, and shelf life

Components of Warthin Starry kit are kept under different storage conditions. Upon receipt, store the components in a dry place and well-closed original packaging at temperature indicated on the label. Do not freeze and avoid exposing to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The expiration date is printed on the product label.

Literature

1. Culling, C.F.A. (1974): Handbook of histopathological and histochemical techniques, 2nd ed., Butterworth, London, UK.
2. Sheehan D.C. et Hrapchak, B.B. (1980): Theory and Practice Histotechnology, 2nd ed., CV Mosby, St. Louis, (MO), pp 52, p 14-167.

Warnings and precautions regarding the materials contained in the product:

H272 May intensify fire; oxidiser.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
H410 Very toxic to aquatic life with long lasting effects.

P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.

WS-12T-IFU_EN10, 16 July 2025, IŠP

	Manufacturer	LOT	Batch code		Consult Instructions for use	Σ	Contains sufficient for <n> tests		Contains hazardous substances
	Date of manufacture	REF	Catalogue number		Caution	CE	European conformity		Fragile, handle with care
	Use-by date	°C	Temperature limit	IVD	*In vitro* diagnostic medical device	UDI	Unique device identifier		

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Version	Description / reason for change	Date
10.	Addition of: the QR code, the section "Additional reagents and materials that can be used in staining", table with the Warnings and precautions, revised table with the symbols	16.07.2025.